Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED AMENDMENT

20 CSR 2220-2.020 Pharmacy Permits. The board is amending sections (1), (2), (3), (4), (6), (7), (9), (10), and (11).

PURPOSE: This board is amending subsection (9)(K) and section (11) of this rule to allow Missouri pharmacies to dispense prescriptions written by an authorized prescriber based on a valid medical evaluation. The board is also amending other provisions of the rule to address signature requirements for entities submitting a pharmacy permit application and to update the rule's current definitions of specific pharmacy classes.

(1) All permits for the operation of a pharmacy shall expire on the date specified by the director of the Division of Professional Registration pursuant to [*4 CSR 230-2.031*] **20 CSR 2231-2.010.**

(2) A pharmacy permit may be issued on the application of the owners. If the owner is a corporation, an officer of the corporation must sign the application as the applicant. If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability company, a member must sign the application as the applicant. In the case where a pharmacy is owned and operated by a person(s) who is a licensed pharmacist and in active charge of the pharmacy, the application for permit can be made by either party. **Alternatively, a pharmacy permit application may be signed by an attorney or other person lawfully granted power of attorney to sign the application on the applicant's behalf. In such case, a representative of the applicant shall review the application for truth and accuracy prior to submitting the application to the board. Proof of a power of attorney designation shall be submitted with the application.**

(3) When a pharmacy changes ownership, the original permit becomes void on the effective date of the change of ownership. Before any new business entity resulting from the change opens a pharmacy for business, it must obtain a new permit from the board. A temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license *[shall]* **may** be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.

(4) If an individual or business entity operating a pharmacy changes the location of the pharmacy to a new facility (structure), the pharmacy shall not open for business at the new location until the board or its duly authorized agent has inspected the premises of the new location

and approved it and the pharmacy as being in compliance with section 338.240, RSMo and all other provisions of the law. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a pharmacy at the new location and the permit shall bear the same number as the previous pharmacy permit. However, the permit remains valid if the pharmacy address changes, but not the location and an amended permit will be issued without charge under these circumstances.

(A) Remodeling of a licensed pharmacy within an existing structure shall be deemed to have occurred when any change in the storage conditions of the Schedule II controlled substances is made or new connections to water/sewer resources are made or any changes in the overall physical security of drugs stored in the pharmacy as defined in *[4 CSR 220-2.010(1)(H)]* **20 CSR 2220-2.010(1)(H)** are made. Remodeling as defined within this section will not require the initiation of any change of location procedures. Satisfactory evidence of plans for any remodeling of a pharmacy must be provided to the board office thirty (30) days in advance of commencing such changes along with an affidavit showing any changes to the pharmacy physical plant and the projected completion date for any remodeling.

(6) No pharmacy permit will be issued unless the pharmacy area is under the direct supervision of a licensed pharmacist in good standing with the Missouri State Board of Pharmacy*[,]* who **is designated as the pharmacist-in-charge and** meets the requirements of *[4 CSR 220-2.090]* **20 CSR 2220-2.090**.

(7) If the owner/applicant is not the licensed pharmacist-in-charge, then the pharmacist-in-charge must meet the requirements of 4 CSR 220-2.090 and complete the pharmacist-in-charge affidavit of the permit application *[and have it notarized]*.

(9) The following classes of pharmacy permits or licenses are hereby established **for entities providing services as defined in section 338.010, RSMo**:

(A) Class A: Community/Ambulatory. A pharmacy that provides services as defined in section 338.010, RSMo to the general public;

(B) Class B: Hospital *[Outpatient]* Pharmacy. *[A pharmacy operated by and located within a hospital that provides services as defined in section 338.010, RSMo to patients other than to the hospital's inpatient population;]* **A pharmacy owned, managed, or operated by a hospital as defined by section 197.020, RSMo, or a clinic or facility under common control, management or ownership of the same hospital or hospital system. This section shall not be construed to require a class B hospital pharmacy permit or license for hospitals solely providing services within the practice of pharmacy under the jurisdiction of, and the licensure granted by, the department of health and senior services under and pursuant to Chapter 197, RSMo;**

(E) Class E: Radiopharmaceutical. A pharmacy that is not open to the general public and provides services as defined in section 338.010, RSMo *[limited to the preparation and dispensing of] that prepares and dispenses* radioactive drugs as defined by the Food and Drug Administration (FDA) **and drugs related to the use of radioactive drugs** to

health care providers for use in the treatment or diagnosis of disease and that maintains a qualified nuclear pharmacist as the pharmacist-in-charge;

(H) Class H: Sterile Product Compounding. A pharmacy that provides services as defined in section 338.010, RSMo and provides a sterile pharmaceutical as defined in 20 CSR 2220-2.200 *[(11)(I) and (AA). Pharmacies providing sterile pharmaceuticals within the exemptions outlined in 20 CSR 2220-2.200(25) shall not be considered a Class H pharmacy]*;

(J) Class J: Shared Service. *[A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations and therapeutic interventions; and]* **A pharmacy engaged in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions;**

(K) Class K: Internet. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the receipt, review, preparation, compounding, dispensing or offering for sale any drugs, chemicals, medicines or poisons for any new prescriptions originating from the Internet for greater than ninety percent (90%) of the total new prescription volume on any day*[. A prescription must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient.*]**;**

(L) Class L: Veterinary. A pharmacy engaged in the sale, dispensing, or filling of a legend drug for use in animals that must only be dispensed by prescription under state or federal law, provided that an additional Class L pharmacy permit shall not be required for pharmacies holding a Class A pharmacy permit that are also engaged in the sale, dispensing, or filling of a legend drug for animal use;

(M) Class M: Specialty (bleeding disorder). A pharmacy that provides blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders, as defined by 20 CSR 2220-6.100;

(N) Class N: Automated dispensing system (health care facility). An automated dispensing system as defined in 20 CSR 2220-2.900 that is located in a facility where medical services are provided to patients on the premises of or at the same physical location as such facility;

(O) Class O: Automated dispensing system (ambulatory care). An automated dispensing system as defined in 20 CSR 2220-2.900 that is not located in a health care facility identified in subsection (9)(N) of this rule; and

(P) Class P: Practitioner office/clinic. A pharmacy that is located in or on the premises of an office or clinic of a healthcare practitioner licensed in the United States who is authorized to prescribe medication by law and that provides pharmacy services as defined in section 338.010, RSMo, solely for patients of such practitioner or

practitioners.

(10) Pharmacy applications for initial licensure or renewals of a license shall accurately note each class of pharmacy that is practiced at the location noted on the application or renewal thereof. The permit (license) issued by the board shall list each class of licensure that the pharmacy is approved to engage in. *[Whenever a change in service classification occurs at a pharmacy the permit must be sent to the board with a notarized statement explaining any additions or deletions of pharmacy classes that are to be made.]* **A Pharmacy Change of Classification Application shall be filed with the board prior to adding or deleting any pharmacy classes with the applicable fee.**

(11) Prescriptions processed by any classification of licensed pharmacy must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a *[sufficient physical examination and clinical assessment of the patient]* **medical evaluation of the patient as required by law**. *[A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.]*

AUTHORITY: section[s] 338.140, RSMo Supp. 2013, and ***section*** *338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.020. Original rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. For intervening history, please consult the* ***Code of State Regulations****. Amended: Filed January 19, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political more than five hundred dollars ($ 500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the Missouri Register. No public hearing is scheduled.